



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Washington, DC 20204

SEP 11 2000

5634 '00 OCT -3 P2:33

Mr. R. Elliott Dunn, Jr.  
General Counsel  
Strictly Supplements, Inc.  
3733 Howard Hughes Parkway  
Suite 290N  
Las Vegas, Nevada 89109

Dear Mr. Dunn:

This is in response to your letter of July 7, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (FD&C Act)). Your submission states that Strictly Supplements, Inc. intends to market a product named Citr-A-Sol as a dietary supplement.

This letter is to advise you that this product can not be lawfully marketed as a dietary supplement because it violates the FD&C Act. The continued marketing of this product as a dietary supplement violates the FD&C Act and may subject you or the product to action under the FD&C Act without further notice.

The product Citr-A-Sol is represented as being a dietary supplement. The product contains, among other ingredients, selegiline. Selegiline is an active ingredient in several approved approved new drug applications and abbreviated new drug applications, including Eldepryl, a prescription drug manufactured by Somerset Pharmaceuticals. 21 U.S.C. 321(ff)(3)(B) states that the term "dietary supplement" does "not include an article that is approved as a new drug" or an article "authorized for investigation as a new drug" which was not before such approval or authorization "marketed as a dietary supplement or as a food." Either an entire product, or any of a product's individual components may be "an article that is approved as a new drug" or an article "authorized for investigation as a new drug" within the meaning of 21 U.S.C. 321(ff)(3)(B). Because selegiline was not marketed as a dietary supplement or as a food before its approval as a new drug, a dietary supplement may not include this ingredient.

Your letter indicates that the product labeling bears the claims "Helps maintain normal function of brain cells and promote a feeling of well-being" and "...to help maintain the normal function of brain cells, which tends to promote the feeling of well-being and enhances the quality of life..." Because this product is not a dietary supplement within the meaning of the FD&C Act, these claims evidence that the product is intended to affect the structure or any function of the body and that it is a drug under

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21 U.S.C. 321(g)(1)(C). Moreover, FDA is aware of other information indicating that Citr-A-Sol is promoted and marketed in a manner that evidences that it is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B) in that it is promoted as a treatment for disease. Therefore, Citr-A-Sol is a new drug under 21 U.S.C. 321(p) that does not have a new drug application approved pursuant to 21 U.S.C. 355. It is therefore illegal to introduce Citr-A-Sol or deliver it for introduction into interstate commerce (21 U.S.C. 331(d)).

Selegiline is also not a dietary ingredient under the definition of a dietary supplement in the FD&C Act. Under 21 U.S.C. 321(ff)(1), a dietary supplement is defined, in part, as a product that contains one or more dietary ingredients that are a "vitamin," a "mineral," an "amino acid," and "herb or other botanical," a "dietary substance for use by man to supplement the diet by increasing the total dietary intake," or a "concentrate, metabolite, constituent, extract, or combination" of any ingredient named above. Selegiline is not a vitamin, mineral, herb or other botanical, or an amino acid (21 U.S.C. 321(ff)(1)(A-D)).

It is also not a "dietary substance for use by man to supplement the diet by increasing the total dietary intake" (21 U.S.C. 321(ff)(1)(E)). The term "dietary substance" is not defined in the FD&C Act or the statute's legislative history. The term must, therefore, be interpreted in accordance with its common, usual meaning. According to Webster's II New Riverside University Dictionary, "dietary" means "of or relating to diet," diet means "an organism's usual food and drink," and "substance" generically refers to "that which has mass, occupies space, and can be perceived." "Dietary substance," therefore, means anything commonly perceived as part of man's usual food or drink. Selegiline is the active ingredient in an approved NDA, specifically, Eldepryl. It is not a part of man's usual food or drink. Indeed, this substance has been known to be associated with significant adverse reactions when used with other drugs or with certain foods and beverages. Nor is it a dietary ingredient described in 21 U.S.C. 321(ff)(1)(F), that is, a concentrate, metabolite, constituent, extract, or combination of any ingredient described above.

Two consequences follow from the conclusion that selegiline is not a dietary ingredient. First, because the claims for the product recited above are in fact claims for selegiline, which is not a dietary ingredient, these claims are not excluded from consideration as evidence that the product is a drug. Citr-A-Sol is therefore intended to affect the structure or function of the body under 21 U.S.C. 321(g)(1)(C). The product is, therefore, a drug, a new drug, and an unapproved new drug and it is illegal to introduce Citr-A-Sol or deliver it for introduction into interstate commerce. Second, because selegiline is not a dietary ingredient defined in 21 U.S.C. 321(ff)(1), it is an ingredient in a dietary supplement that is not exempt under 21 U.S.C. 321(s)(6) from the food additive provisions of the Act. Because it is not exempt, it is an ingredient that must be generally recognized as safe

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(GRAS) or an approved food additive. As stated above, selegiline may result in serious adverse reactions when used in combination with certain drugs, foods, or drinks. FDA is not aware of any evidence that would demonstrate that it is GRAS and it is not an approved food additive. For these reasons, a dietary supplement that contains selegiline is adulterated under 21 U.S.C. 342(a)(1), 342(f)(1)(A), and 342(a)(2)(C).

Please contact us if you have any questions regarding this matter.

Sincerely,

Handwritten signature of John B. Foret in black ink.

John B. Foret  
Director

Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling,  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Office of Compliance, Center for Drug Evaluation and Research, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, San Francisco District Office, Office of Compliance, HFR-PA140

FDA, Florida District Office, Office of Compliance, HFR-SE 240

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cc:

HFA-224 (w/incoming)

HFA-305 (docket 97S-0163)

HFD-40 (Behrman)

HFD-310

HFD-314

HFS-22 (CCO)

HFS-800 (r/f, file)

HFS-810

HFS-811 (file)

HFS-607 (Delgado)

HFV-228 (Benz)

GCF-1 (Dorsey, Nickerson, Fox, Jones)

r/d:HFS-811:RMoore:8/30/00

revised per GCF-1:DDorsey:9/7/00

f/t:HFS-811:rjm:9/7/00:docname:71480.adv:disc50

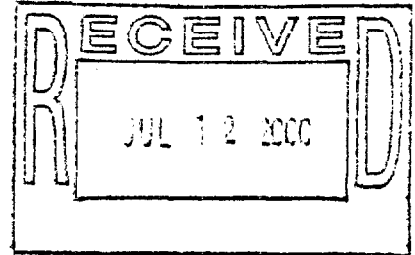
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**S**trictly  
Supplements, Inc.  
3733 Howard Hughes Parkway, Suite 290N  
Las Vegas, NV 89109

7/14/00

July 7, 2000

Office of Special Nutritionals (HFS-50)  
Center for Food Safety and Applied Nutrition  
200 C Street SW  
Washington, D.C. 20204



**RE: Notice of Use of § 403(r)(6) Statements on  
Dietary Supplement Labels and Labeling**

Gentlemen:

Pursuant to the requirements contained in 21 C.F.R. § 101.93, this is to notify your office of the following information with respect to one dietary supplement distributed by Strictly Supplements, Inc. 3733 Howard Hughes Parkway, Suite 290N, Las Vegas, Nevada 89109. The name of the dietary supplement, and the text of the statements used on or in the label or labeling of the product, is as follows:

Citr-A-Sol - "Helps Maintain Normal Function of Brain Cells and Promote a Feeling of Well-Being" and "... to help maintain the normal function of brain cells, which tends to promote the feeling of well-being and enhances the quality of life ..."

Photocopies of the label and labeling for this supplement are included with this notice. The undersigned certifies that Strictly Supplements, Inc. has information to substantiate that the statements made are truthful and are not misleading, and that the information contained herein is accurate and complete.

Sincerely,

R. Elliott Dunn, Jr.  
General Counsel

| <p><b>SUPPLEMENT FACTS</b></p> <p>Serving Size 1 drop<br/>Servings Per Container 600</p> <table border="1"> <thead> <tr> <th>Amount Per Serving</th> <th>% Daily Value</th> </tr> </thead> <tbody> <tr> <td>Proprietary Blend 1mg</td> <td>**</td> </tr> <tr> <td>Citric Acid</td> <td>**</td> </tr> <tr> <td>Distilled Water</td> <td>**</td> </tr> <tr> <td>Glycerol</td> <td>**</td> </tr> <tr> <td>Selegiline</td> <td>**</td> </tr> </tbody> </table> <p>** Daily Value not established</p> | Amount Per Serving | % Daily Value | Proprietary Blend 1mg | ** | Citric Acid | ** | Distilled Water | ** | Glycerol | ** | Selegiline | ** | <p><b>Citr-A-Sol</b><br/>DIETARY SUPPLEMENT</p> <p>DEVELOPED BY<br/><b>DEDI</b></p> <p>Contents: 25ml</p> <p>Distributed by:<br/><b>Strictly Supplements, Inc.</b><br/>3733 Howard Hughes Parkway, Suite 290N<br/>Las Vegas, NV 89109</p> | <p><b>DIRECTIONS:</b> Take one or more drops according to the chart in the package insert.</p> <p><b>STORAGE:</b> Refrigerate when possible.</p> <p><b>PRECAUTIONS:</b> As with any supplement, do not use if taking prescription medication, pregnant, or nursing a baby without first contacting a physician.</p> <p>Read package insert prior to using this product.</p> <p>Keep out of reach of children.</p> <p>Expiration Date: _____</p> <p>Lot #: _____</p> |
|--|--------------------|---------------|-----------------------|----|-------------|----|-----------------|----|----------|----|------------|----|---|---|
| Amount Per Serving   | % Daily Value      |               |                       |    |             |    |                 |    |          |    |            |    |   |   |
| Proprietary Blend 1mg  | **                 |               |                       |    |             |    |                 |    |          |    |            |    |   |   |
| Citric Acid  | **                 |               |                       |    |             |    |                 |    |          |    |            |    |   |   |
| Distilled Water  | **                 |               |                       |    |             |    |                 |    |          |    |            |    |   |   |
| Glycerol   | **                 |               |                       |    |             |    |                 |    |          |    |            |    |   |   |
| Selegiline   | **                 |               |                       |    |             |    |                 |    |          |    |            |    |   |   |

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|--|--|--|-----------------------|----|-------------|----|-----------------|----|----------|----|------------|----|--|---|
| Amount Per Serving   | % Daily Value  |  |                       |    |             |    |                 |    |          |    |            |    |  |   |
| Proprietary Blend 1mg  | **   |  |                       |    |             |    |                 |    |          |    |            |    |  |   |
| Citric Acid  | **   |  |                       |    |             |    |                 |    |          |    |            |    |  |   |
| Distilled Water  | **   |  |                       |    |             |    |                 |    |          |    |            |    |  |   |
| Glycerol   | **   |  |                       |    |             |    |                 |    |          |    |            |    |  |   |
| Selegiline   | **   |  |                       |    |             |    |                 |    |          |    |            |    |  |   |
| <p>Do Not Use if Seal On Tube Container Is Broken</p> <p>Expiration Date: _____</p> <p>Lot #: _____</p>  | <p>*This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.</p> | <p>Distributed by:<br/><b>Strictly Supplements, Inc.</b><br/>3733 Howard Hughes Parkway<br/>Suite 290N<br/>Las Vegas, NV 89109</p> |                       |    |             |    |                 |    |          |    |            |    |  |   |

# Citr-A-Sol

## (GENERAL INFORMATION ABOUT THE PRODUCT)

### USAGE CONDITIONS AND AMOUNTS

If you take Citr-A-Sol to help maintain the normal function of brain cells, which tends to promote the feeling of well-being and enhances the quality of life, ★★ it is suggested that you take it in the following amounts according to your age. Remember, one drop is equal to one mg.

(Recommended Daily & Weekly Amounts Below)

| <u>AGE</u> | <u>AMOUNT</u>         |
|------------|-----------------------|
| 30-35      | 1 mg two times a week |
| 35-40      | 1 mg every second day |
| 40-45      | 1 mg daily            |
| 45-50      | 2 mg daily            |
| 50-55      | 3 mg daily            |
| 55-60      | 4 mg daily            |
| 60-63      | 5 mg daily            |
| 63-70      | 6 mg daily            |
| 70-75      | 9 mg daily            |
| 80 +       | 10 mg daily           |

If you take 6 mg or more daily, it is suggested that you divide the amount in half, and take one-half in the early morning and one-half in the afternoon. Citr-A-Sol is best kept refrigerated after it is opened and maintains its purity until the stated expiration date. Kept frozen Citr-A-Sol will maintain its purity indefinitely. Store in tube container to keep out of direct light.

★★ This statement has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.

## PRECAUTIONS

Certain side effects may occur with the use of any product, although there are no such known or reported effects from the use of Citr-A-Sol. There are certain precautions, however, that should be taken with the use of this product, as with many other safe and effective products. These include:

- Use only as directed in this package insert. Keep product from excessive heat or light. As with any supplement, do not use if taking a prescription medication, pregnant, or nursing a baby without first contacting a physician.
- Keep out of reach of children.
- Do not use if seal on tube is broken by someone other than yourself.
- Do not use more than the amounts recommended in this package insert, except upon the advice of a physician.
- If any adverse side effects should occur discontinue use and contact a physician or nearest poison control center.

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Las Vegas, NV 89109